

### Remarks

Claims 50-53 and 55-59 remain pending in the application. Claims 50-53 and 55-59 have been amended herein. Claims 1-49, 54, and 60 - 102 have been canceled. No new matter has been added by this amendment.

For the purpose of clarifying issues on appeal, all claims have been amended to include a specific concentration range of the surfactant SDS as provided in rejected claims 53 and 58, i.e., SDS within the range of 0.003% to 0.01%. Amendments presenting rejected claims in better form for consideration on appeal may be admitted after a final rejection. 37 C.F.R. §1.116 (b).

### Claim Rejections – 35 U.S.C. § 112

Claims 1 – 102 were rejected under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The use of the term “ionophoric” was at issue. The term is not in the present claims. It is Applicant’s contention that one of ordinary skill in the art would appreciate that at the time the application was filed Applicant had possession of the claimed invention, i.e., one of ordinary skill in the art would recognize that the surfactants utilized could be characterized as having ionophoric properties. *See, Mohan, Lawrence, Dow.*

### Claim Rejections – 35 U.S.C. § 112

Claims 1-102 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 18, 44 and 86 have been canceled. Claims 126-18, 23-25, 38-46, 61-65, 73-78, 84 and 85 have been canceled. Claims 22 and 92 have been canceled. Reconsideration of the rejection is requested.

Claim Rejections – 35 U.S.C. § 102(b) – Lai et al

Claim 1, 3, 8-12, 15, 17, 18, 20 22, 24, 26-38, 42, 44, 49-53, 60, 61, 65-69, 71, 81-84, 86, 87, 90, 92, 93, 95, 96 and 100 were rejected under 35 U.S.C. §102(b) as being anticipated by Lai et al.

Claim 53 has been amended to include the limitations of claim 49. This amendment places the application in better form for appeal by materially reducing the issues for appeal.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. M.P.E.P. §2131.

Lai et al. discloses a solution of 30:70 THF:SDS, 0.07M SDS. An SDS concentration of 0.07M equates to approximately 2.02%. See, attached SDS Calculation sheet. Unlike the present invention, Lai et al. teaches surfactant concentration ranges of SDS at micellar concentrations. Micelles are colloidal particles consisting of many molecules. Stedmans Medical Dictionary. Solutions of surfactants above a critical micellar concentration (CMC) are often used to facilitate solubility of compounds, the micellar complexes of ion surfactants allowing incorporation of water insoluble substrates in the hydrophobic part. Bagno, p. 1079. The concentration of SDS of Lai et al. would not promote ionophoric behavior as the surfactant concentrations are above the respective critical micelle concentrations (CMC for SDS is approximately 0.23%). See, Reddi et al., Critical Micelle Concentrations of Aqueous Surfactant Systems, NSRDS-NBS 36. Calculations reveal that the concentration of SDS in Lai et al. is approximately 10 times greater than the critical micelle concentration (and at least approximately 25 times greater than the highest concentration of SDS of the present claims).

The claims as amended are directed to specific non-micelle forming concentration ranges of SDS. The use of SDS at the micellar concentrations of Lai and Reddi is to facilitate solubility of porphyrin through micelle formation. Reddi, p. 642 – 643. SDS in Lai et al. is provided at concentrations at which the surfactant does not function as ionophores. Williams et al also teaches the use of surfactants at micellar concentrations to facilitate solubility of compounds.

A proposed modification of Lai et al. to lower the concentrations of SDS to the presently claimed ranges would not be obvious as such a modification would render the prior art invention

unsatisfactory for its intended purpose, i.e. to improve the solubility of poorly soluble porphyrin (surfactant concentrations above CMC are necessary to form micellar complexes and improve solubility). See, M.P.E.P §2143.01, citing *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).

Furthermore, any proposed modification of Lai et al to lower the concentration of SDS to the presently claimed ranges would not be obvious as such a modification would change the principle of operation of the prior art invention being modified. See, M.P.E.P §2143.01, citing *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959). The presently claimed concentration range of SDS would not be an obvious variation of the teachings of Lai et al., as such modifications would render the prior art invention unsatisfactory for its intended purpose, i.e., to improve the solubility of poorly soluble porphyrin. Further, any proposed modification of Lai et al. to lower the concentration of SDS to the presently claimed ranges would not be obvious as such modification would change the principle of operation of the prior art invention being modified.

**Claim Rejections – 35 U.S.C. § 102(b) – Nitzan**

Claim 1-3, 6, 8, 10-12, 15, 18, 26, 30, 32, 37, 39, 44, 45, 48, 49, 51, 52, 80-83, 85-89, 92, 95, 97 and 101 were rejected under 35 U.S.C. §102(b) as being anticipated by Nitzan.

Claims 51 and 52 remain pending. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. M.P.E.P. §2131.

Claims 51 and 52 have been amended to be dependent on claim 53. Nitzan discloses the use of polymyxin nonapeptide (PMNP). Nitzan does not disclose or suggest the use of SDS. For the reasons set forth above with regard to claim 53, reconsideration of this rejection is requested.

**Claim Rejection: 35 U.S.C. §103 – Swartz Nitzan Williams**

Claims 1, 4, 5, 10, 13, 14, 17, 23, 26-28, 34, 36, 40, 41, 43, 46, 47, 54-57, 59-64, 72-76, 78 and 79 were rejected under 35 U.S.C. §103(a) as being unpatentable over Swartz in combination with Nitzan et al and Williams et al. Claims 55 – 57 and 59 remain pending. No

combination of the references would teach or suggest the claim limitation of a specific concentration range of SDS. To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

**Claim Rejection: 35 U.S.C. §103 Swartz Nitzan Williams**

Claims 9, 19-22, 95, 98 and 99 were rejected under 35 U.S.C. §103(a) as being unpatentable over Swartz in combination with Nitzan et al and Williams et al. All of these claims have been canceled.

**Claim Rejection: 35 U.S.C. §103 Wilk Nitzan**

Claim 16 was rejected under 35 U.S.C. §103(a) as being unpatentable over Wilk et al in combination with Nitzan et al. Claim 16 has been canceled.

**Claim Rejection: 35 U.S.C. §103 Lai et al Nitzan et al**

Claims 10, 25, 60, 70, 87, and 91 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lai et al in combination with Nitzan et al. All of these claims have been canceled.

**Claim Rejection: 35 U.S.C. §103 -Swartz Nitzan Williams**

Claims 58 and 77 were rejected under 35 U.S.C. §103(a) as being unpatentable over Swartz et al in combination with Nitzan and Williams, and further in view of Singer et al.

No combination of the references would teach or suggest the claim limitation of a specific concentration range of SDS. To establish prima facie obviousness of a claimed invention, all the

claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).

**Claim Rejection: Double Patenting**

Claims 1-102 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,251,127 in view of Rothstein. It is respectfully submitted that the claims as now amended define an invention which is not merely an obvious variation of an invention claimed in U.S. Patent No. 6,251,127. Neither reference teaches or suggests the use of SDS at the concentration range as presently claimed.

Applicant respectfully requests that the Examiner enter the above amendments to place the rejected claims in better form for consideration on appeal.

Please direct any questions regarding this application to John Klos at (612) 321-2806.

Respectfully submitted,  
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(Marked-Up Version Showing Application as Amended 2/11/2003)

In the Claims:

Cancel claims 1 - 49.

50. (amended) The method of photodynamic disruption of cells of claim [49] 53 wherein the step of identifying an area of cell activity includes an examination of a portion of a living body.

51. (amended) The method of photodynamic disruption of cells of claim [49] 53 wherein the light wavelength ranges from about 400 nm to about 800 nm, the light dosage ranges from about 10 J/cm<sup>2</sup> to about 100 J/cm<sup>2</sup> and the light dosage rate ranges from about 50 mw/cm<sup>2</sup> to about 200 mw/cm<sup>2</sup>.

52. (amended) The method of photodynamic disruption of cells of claim [49] 53 wherein the wavelength ranges from about 600 nm to about 700 nm.

53. (amended) A method of photodynamic disruption of cells comprising the steps of:

identifying an area of cell activity;

applying a concentration including a combination of a surfactant and a photosensitizing agent to the area of cell activity, said surfactant disorienting a cell membrane so that said membrane no longer functions as an effective osmotic barrier, and so that said photosensitizing agent is able to pass through the disoriented cell membrane; and

exposing the area of cell activity to light having a light wavelength, light dosage and a light dosage rate to cause photodynamic cellular disruption, [The method of photodynamic disruption of cells of claim 49] wherein the surfactant is SDS provided in a solution having an SDS concentration range of between 0.003 % to 0.01%.

Cancel claim 54.

55. (amended) The method of photodynamic disruption of acellular organisms of claim [54] 58, wherein the step of identifying an area of acellular organism activity includes an examination of a portion of a living body.

56. (amended) The method of photodynamic disruption of acellular organisms of claim [54] 58, wherein the light wavelength ranges from about 400 nm to about 800 nm, the light dosage ranges from about 10 J/cm<sup>2</sup> to about 100 J/cm<sup>2</sup> and the light dosage rate ranges from about 50 mw/cm<sup>2</sup> to about 200 mw/cm<sup>2</sup>.

57. (amended) The method of photodynamic disruption of acellular organisms of claim [54] 58 wherein the wavelength ranges from about 600 nm to about 700 nm.

58. (amended) A method of photodynamic disruption of acellular organisms comprising the steps of:

identifying an area of acellular organism activity;

applying a concentration including a combination of a surfactant and a photosensitizing agent to the area of acellular organism activity, said surfactant disorienting an acellular organism membrane so that said membrane no longer functions as an effective osmotic barrier, and so that said photosensitizing agent is able to pass through the disoriented acellular organism membrane; and

exposing the area of acellular organism activity to light having a light wavelength, light dosage and a light dosage rate. [The method of photodynamic disruption of acellular organisms of claim 54] wherein the surfactant is SDS provided in a solution having an SDS concentration range of between 0.003 % to 0.01%.

59. (amended) The method of photodynamic disruption of acellular organisms of claim [54] 58 wherein the step of identifying an area of acellular activity includes the step of identifying an area of virus activity.

Cancel claims 60 – 102.

**SDS CALCULATION****SDS Molar to Percentage Calculation For 0.07 M Concentration in Lai Patent****Note:**

$$M(olar) = \frac{\text{moles gram}}{L}$$

**Step One:**

$$\text{moles} \times \frac{\text{molecular weight}}{1 \text{ Liter}} \times \frac{1 \text{ Liter}}{1000 \text{ mL}} = \text{g}/1000\text{mL}$$

**Step Two:**

$$\text{g}/1000\text{mL} \times 0.1 = \text{g}/100 \text{ mL} = \%$$

**Summary Equation:**

$$\frac{(\text{moles})(\text{molecular weight})}{10} = \%$$

**Therefore:**

$$\star \quad 0.07 \text{ M} = 2.0188\%$$

$$\frac{(0.07 \text{ moles})(288.4 \text{ molecular weight})}{10} = 2.0188\%$$

molecular weight of SDS is 288.4